K082634

510(k) Summary for VertiGONE BPPV Goggle

In accordance with the requirements of 21 CFR 807.92, VertiGONE Inc. is hereby submitting a 510(k) Summary for the VertiGONE BPPV Goggle.

1. **Submitter:**

Phillip F. Anthony, MD
President/ CEO
VertiGONE, Inc.
901 Hemphill
Ft. Worth, TX 76104
817-336-6022 Telephone
817-332-2304 Fax

APR - 7 2009

24/March/2009

2. **Contact Person:**

Jaye Thompson, Ph.D.
Senior Vice President Clinical Operations
inVentiv Clinical Solutions
2202 Timberloch Place, Suite 230
Fort Worth, Texas 76104
Tel: 281.367.6655
Fax: 281.367.9679
Email: JThompson@inventivclinical.com

3. **Device Classification:**

Trade name: VertiGONE BPPV Goggle
Common name: VertiGONE goggles
Classification Name: Vestibular Analysis Apparatus
Product Classification: Unclassified
Product Code: LXV
Regulation Number: Pre-amendment

Panel: Ear, Nose and Throat

4. **Predicate Device:**

Device: BRU™ - Balance Rehabilitation Unit

Manufacturer: Medicaa (Uruguay) S.A.

Approval 510(k) #: K070085

5. **Device Description:**

The VertiGONE BPPV Goggle is a head mounted medical device worn by the patient. The VertiGONE Goggle is designed as a non-intrusive device with non-substantial risk to the subjects. The subject device consists of a molded plastic goggle, an elastic strap to secure the goggle to the head, and a visual reference platform including two visual reference mechanisms. The VertiGONE Goggle provides a visual reference platform for the practitioner to guide the patient to accurately conduct the Epley, or canalith repositioning, maneuver. When using the device, the patient and/or the practitioner are each provided with visual references. Thus, the practitioner can help the patient to complete the Epley maneuver more accurately.

6. **Indications for Use:**

The VertiGONE goggle is indicated for the treatment of Benign Paroxysmal Positional Vertigo (BPPV). The VertiGONE goggle guides the practitioner to move the patient's head accurately through the Epley, or canalith repositioning maneuver.

7. **Performance Data**

Clinical Data

The clinical testing was conducted in a controlled practitioner office environment and submitted as part of the 510(k) application to confirm that VertiGONE goggles improve rotary nystagmus scores, and thus BPPV, by aiding the physician in accurately performing the Classical Epley, or canalith repositioning, maneuver in the treatment of BPPV. The controlled clinical design was a prospective, single-blind crossover study. The VertiGONE Goggle has been demonstrated to be helpful in the management of BPPV. The results of the clinical trial suggest moderate improvement in BPPV outcomes in patients when the Epley maneuver was performed correctly using VertiGONE verse outcomes when a less accurate Epley maneuver was performed.

8. **Technological Characteristics and Substantial Equivalence**

The VertiGONE BPPV Goggle and its predicate devices are all devices that use either visual reference platform or static force platform to help the practitioner to visually treat/train patients with vertigo. Although there are differences in the technological characteristics of the VertiGONE BPPV Goggle and its predicate devices, those differences do not raise new questions of safety. Evidence of efficacy was collected in a controlled clinical study.

VertiGONE, Inc. believes that, based on the results of clinical performance data, the VertiGONE BPPV Goggle is substantially equivalent to other legally marketed devices for the treatment of benign paroxysmal positional vertigo (BPPV).

9. Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed device has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

VertiGONE, Inc
c/o Jaye Thompson, PhD.
inVentiv Clinical Solutions
2202 Timberloch Place, Suite 230
Woodlands, Texas 77380

APR - 7 2009

Re: K082634
Trade Name: VertiGONE BPPV Goggle
Regulatory Class: unclassified
Product Code: LXV
Dated: March 24, 2009
Received: March 26, 2009

Dear Dr. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

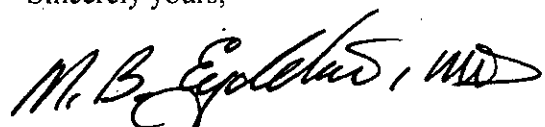
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082634

Device Name: Vertigone BPPV Goggle

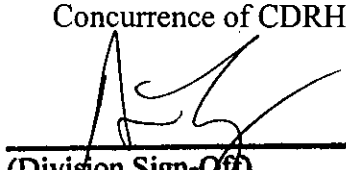
Indications for Use:

The VertiGONE goggle is indicated for the treatment of Benign Paroxysmal Positional Vertigo (BPPV). The VertiGONE goggle guides the practitioner to move the patient's head accurately through the Epley, or canalith repositioning maneuver.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K082634